

Amendment in Response to March 21, 2008 Office Action
Appl. No. 09/431,519
July 21, 2008

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Amended Claims

Please amend the claims as follows:

Claims 1-42 (canceled).

43. (currently amended) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth, and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation consisting essentially of zeranol and a diluent, and (ii) a controlled-release formulation consisting essentially of zeranol, ~~a controlled-release agent~~ **ethyl cellulose**, and a diluent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

44. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:2 to 1:25 in said composition.

45. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:2 to 1:10 in said composition.

46. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:3 to 1:8 in said composition.

47. (previously presented) The implant composition of claim 43, wherein said composition is subcutaneously injectable in said cattle.

48. (previously presented) The implant composition of claim 43, wherein zeranol comprises from about 50 wt.% to about 95 wt.% of said composition based on a total weight percentage basis.

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49. **(previously presented)** The implant composition of claim 43, wherein zeranol comprises from about 60 wt.% to about 80 wt.% of said composition based on a total weight percentage basis.

Claim 50 (canceled).

51. **(previously presented)** The implant composition of claim 43, wherein said diluent of said controlled-release formulation is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

52. **(previously presented)** The implant composition of claim 51, wherein said diluent of said controlled-release formulation is lactose.

Claims 53-55 (canceled).

56. **(previously presented)** The implant composition of claim 43, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

57. **(previously presented)** The implant composition of claim 43, further comprising a bulking agent, binder, excipient, tableting agent, colorant and combinations thereof.

58. **(currently amended)** An anabolic implant composition for stimulating increased rate of growth, greater amount of growth, and greater feed efficiency in cattle, wherein:
said composition comprises:

(i) an immediate-release formulation comprising:

a single anabolic agent consisting essentially of zeranol,

and

a diluent, and

no controlled-release agent, and

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(ii) a controlled-release formulation comprising:

a single anabolic agent consisting essentially of zeranol,
a diluent, and
a controlled-release agent; **[[and]]**

said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation; and

said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:2 to 1:25 in said composition.

Claim 59 (canceled).

60. **(previously presented)** The implant composition of claim 58, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:2 to 1:10 in said composition.

61. **(previously presented)** The implant composition of claim 58, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range of from 1:3 to 1:8 in said composition.

62. **(previously presented)** The implant composition of claim 58, wherein said composition is subcutaneously injectable in said cattle.

63. **(previously presented)** The implant composition of claim 58, wherein zeranol comprises from about 50 wt.% to about 95 wt.% of said composition based on a total weight percentage basis.

64. **(previously presented)** The implant composition of claim 58, wherein zeranol comprises from about 60 wt.% to about 80 wt.% of said composition based on a total weight percentage basis.

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65. (previously presented) The implant composition of claim 58, wherein said diluent of said immediate-release formulation and said diluent of said controlled release formulation are individually selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

Claim 66 (canceled).

67. (previously presented) The implant composition of claim 65, wherein said diluent of said immediate-release formulation and said diluent of said controlled release formulation are both lactose.

68. (currently amended) The implant composition of claim ~~[[65]]~~ 58, wherein said controlled-release agent in said controlled-release formulation is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

69. (currently amended) The implant composition of claim ~~[[65]]~~ 58, wherein said controlled-release agent in said controlled-release formulation is poly(D,L-lactide-co-glycolide).

70. (currently amended) ~~[[The]]~~ An anabolic implant composition of claim 68, for stimulating increased rate of growth, greater amount of growth, and greater feed efficiency in cattle, wherein:

said composition comprises:

(i) an immediate-release formulation comprising:

a single anabolic agent consisting essentially of zeranol,

and

a diluent, and

no controlled-release agent, and

(ii) a controlled-release formulation comprising:

a single anabolic agent consisting essentially of zeranol,

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a diluent, and
~~said controlled-release agent in said controlled-release~~
~~formulation is~~ ethyl cellulose;
said immediate-release formulation and said controlled-release formulation
cooperate to effect said stimulation; and
said diluent of said immediate-release formulation and said diluent of said
controlled release formulation are individually selected from the group consisting of
lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and
combinations thereof.

71. (previously presented) The implant composition of claim 58, wherein said controlled-release agent in said controlled-release formulation comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

72. (previously presented) The implant composition of claim 58, further comprising a bulking agent, binder, excipient, tableting agent, colorant and combinations thereof.

73. (previously presented) The implant composition of claim 58, wherein said diluent of said immediate-release formulation is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

74. (previously presented) The implant composition of claim 73, wherein said diluent of said immediate-release formulation is lactose.

Claim 75 (canceled).

76. (previously presented) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation consisting essentially of zeranol and lactose, and (ii) a controlled-release formulation consisting essentially of zeranol, lactose, a suitable

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plasticizer and ethyl cellulose, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

77. **(previously presented)** The implant composition of claim 76 wherein the suitable plasticizer is triacetin.

78. **(withdrawn)** A method for stimulating increased rate of growth, greater amount of growth, and greater feed efficiency in cattle, wherein the method comprises administering an anabolic implant composition of claim 43 to the cattle.

79. **(withdrawn)** The method of claim 78, wherein the immediate-release formulation and the controlled-release formulation are present in the composition in a weight ratio of from 1:2 to 1:25.

80. **(withdrawn)** The method of claim 78, wherein the administration comprises subcutaneously injecting the composition into the cattle.

81. **(withdrawn)** The method of claim 78, wherein zeranol is from about 50 wt.% to about 95 wt % of the composition.

82. **(withdrawn)** The method of claim 78, wherein zeranol is from about 60 wt.% to about 80 wt % of the composition.

83. **(withdrawn)** The method of claim 78, wherein the diluent in the immediate release formulation comprises one or more diluents selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

84. **(withdrawn)** The method of claim 78, wherein the diluent in the immediate release formulation comprises lactose.

Claims 85-87 (canceled).

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88. **(withdrawn)** The method of claim 78, wherein the composition further comprises a bulking agent, binder, tableting agent, excipient, colorant and combinations thereof.

Claims 89-93 (canceled).

Please add the following new claims:

94. **(withdrawn - new)** A method for stimulating increased rate of growth, greater amount of growth, and greater feed efficiency in cattle, wherein the method comprises administering an anabolic implant composition of claim 58 to the cattle.

95. **(withdrawn - new)** The method of claim 94, wherein the immediate-release formulation and the controlled-release formulation are present in the composition in a weight ratio of from 1:2 to 1:10.

96. **(withdrawn - new)** The method of claim 94, wherein the immediate-release formulation and the controlled-release formulation are present in the composition in a weight ratio of from 1:3 to 1:8.

97. **(withdrawn - new)** The method of claim 94, wherein the administration comprises subcutaneously injecting the composition into the cattle.

98. **(withdrawn - new)** The method of claim 94, wherein zeranol is from about 50 wt.% to about 95 wt % of the composition.

99. **(withdrawn - new)** The method of claim 94, wherein zeranol is from about 60 wt.% to about 80 wt % of the composition.

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100. **(withdrawn - new)** The method of claim 94, wherein the diluent in the immediate release formulation comprises one or more diluents selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

101. **(withdrawn - new)** The method of claim 94, wherein the diluent in the immediate release formulation comprises lactose.

102. **(withdrawn - new)** The method of claim 94, wherein the controlled-release agent comprises an agent selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

103. **(withdrawn - new)** The method of claim 94, wherein the controlled-release agent comprises poly(D,L-lactide-co-glycolide).

104. **(withdrawn - new)** The method of claim 94, wherein the controlled-release agent comprises ethyl cellulose.

105. **(withdrawn - new)** The method of claim 94, wherein the composition further comprises a bulking agent, binder, tableting agent, excipient, colorant and combinations thereof.